K053029

JAN 6 2006

Attachment 1 - 510 (k) SUMMARY

510(k) summary for NDR+ – DIVA-D

Identification

Applicant	NICAL SPA 43 Via Soffredini Milan (MI), ITALY 20126 Registration Number: 3003314115
Contact Person	Mr. Roberto Niccolucci - President
Telephone (applicant)	+39 022571110
Designated Agent in the US	Mr. Gerald Silverman 71 Rose Street Hasting On Hudson, NY 10706 Phone: +1 914 674 1085
Manufacturing site	NICAL SPA 43 Via Soffredini Milan (MI), ITALY 20126 Registration Number: 3003314115

Trade name: NDR+/DIVA-D
Common name: Digital image acquisition system
Classification:
The equipment is classified as a class II

CFR21- 892.2050: Picture archiving and communication system

CFR21 - 892.1650: Image Intensified Fluoroscopic X-ray system.

Substantial equivalent device: the NDR+/DIVA-D is defined as Substantially Equivalent (SE) to the INFIMED Platinum ONE digital image acquisition system (certified under the name ORION) (K012490).

The following table compares the NDR+/DIVA-D and the predicate device

FEATURES	*NICAL (NDR+/DIVA D)*	*INFIMED (Platinum ONE)*
Intended use	The NICAL NDR+ is a digital image acquisition system to be used in conjunction with an image Intensifier during radiography or fluoroscopy x-ray examination to capture images by a camera, digitalize the image, review images and format images according to DICOM 3.0 protocol to be sent through network connection	The INFIMED Orion Fluoroscopic imaging system is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed. The Orion system allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1024x1024) may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques. The Orion system enables the operator to hardcopy image with a laser printer or send images over a network. The major system components include: a fluoroscopic TV camera, monitors, and an image processor.
Image Acquisition	CCD camera 1024x1024 12 bit	CCD camera 1024x1024 12 bit
Speed Acquisition	1024x1024 at 25 fps for FLUORO and all radiographic exams	Up to 30 fps for FLUORO acquisition and up to 15 fps for spot acquisition
Edge Enhancer	Completely hardware in real time	Software package
Start Up System	Automatic hardware and software test for each ignition	Automatic system calibration and remote system diagnostics
Noise Reduction	Dynamic recursive filter which offering an automatic noise/blurring optimization effect it gives zero persistence	Standard recursive filter
Image Storage	Up to 36000 frames with matrix 1024x1024. All the images are stored directly from the CCD camera head without any kind of edge enhancement and digital compression.	NA
Post Processing Working	All the images stored in the system can be elaborated in order to modify the windowing, the gray scale, the zoom, the annotation package, the edge enhancement and the noise reduction	Brightness/contrast polarity enhancement. Measurement and annotation package

DSA Application	Real time mask subtraction, road mapping, land marking, pixel shift function, auto loop replay, injector synchronization, automatic or manual possibility to change the mask, maxop function and stepping angio	Real time mask subtraction, road mapping, land marking, percent Stenosis vascular package, auto loop replay, injector synchronization.
Multi Image	Thumbnail image viewing with the possibility to choose the first image for every run or the 50% of the run.	Thumbnail image viewing
DICOM Functions	Full DICOM 3.0 integrated	Full DICOM 3.0 integrated
Laser Interface	When DICOM network is not available in the site installation, it is possible to send the images to a laser printer using the protocol P831 or P859	NA
Interface Commands	Flat keyboard with waterproof surface	Standard pc keyboard + standard pc mouse

Indication for use.

The indication for use of the NDR+/DIVA-D is: **DIGITAL IMAGE ACQUISITION SYSTEM TO BE USED IN CONJUCTION WITH AN IMAGE INTESIFIER DURING RADIOGRAPHY OR FLUOROSCOPY X-RAY EXAMINATION TO CAPTURE IMAGES BY A CAMERA, DIGITALIZE THE IMAGE, REVIEW IMAGES AND FORMAT IMAGES ACCORDING TO DICOM PROTOCOL TO BE SENT THROUGH NETWORK CONNECTION**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

NICAL SPA
% Mr. Gerald Silverman
Designated Agent
71 Rose Street
Hasting on Hudson, NY 10706

AUG 23 2013

Re: K053029
Trade/Device Name: NDR+/DIVA-D
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 27, 2005
Received: November 25, 2005

Dear Mr. Silverman:

This letter corrects our substantially equivalent letter of January 6, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

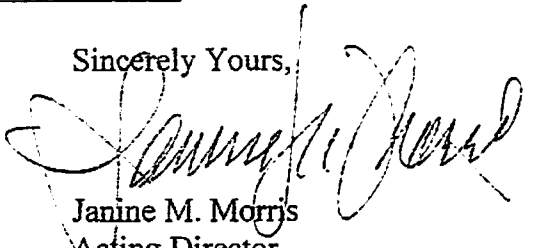
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

6.1. Indication for use Statement

510(k) Number: K053029

Device Name: **NDR+** or **DIVA-D**

The indication for use of the **NDR+/DIVA-D** is: **DIGITAL IMAGE ACQUISITION SYSTEM TO BE USED IN CONJUCTION WITH AN IMAGE INTESIFIER DURING RADIOGRAPHY OR FLUOROSCOPY X-RAY EXAMINATION TO CAPTURE IMAGES BY A CAMERA, DIGITALIZE THE IMAGE, REVIEW IMAGES AND FORMAT IMAGES ACCORDING TO DICOM PROTOCOL TO BE SENT THROUGH NETWORK CONNECTION**

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053029

Prescription Use ✓